

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of:)
)
Manfred BOHN et al.) Group Art Unit: 1614
)
Application No.: 09/077,194) Examiner: V. Kim
)
Filed: May 26, 1998)
)
For: USE OF 1-HYDROXY-2-)
PYRIDONES FOR THE)
TREATMENT OF SEBORRHEIC)
DERMATITIS)

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REPLY BRIEF UNDER 37 C.F.R. § 1.193(b)(1)

In response to the Examiner's Answer (Paper No. 34) mailed on April 9, 2003,
Appellants respectfully submit this Reply Brief in triplicate under 37 C.F.R.
§ 1.193(b)(1). **A Request for Oral Hearing accompanies this Reply Brief.**

REMARKS

I. Item No. 2 Was Addressed in the Appeal Brief.

The Examiner mistakenly states that the Appeal Brief "does not contain a statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal."

Answer at pages 1-2. On the contrary, Appellants stated: "To the best of the undersigned's knowledge, there are no related appeals or interferences known to Appellants, the Appellants' legal representative, or Assignee which will directly affect or be directly affected by or have a bearing on the Board's decision in the present appeal." Appeal Brief at 2.

II. Appellants Acknowledge that the Claims on Appeal Are Found in Appendix B.

Appellants thank the Examiner for entering their Amendment under 37 C.F.R. § 1.116, filed with their Appeal Brief on December 16, 2002. Accordingly, the present form of the appealed claims can be found in Appendix B of the Appeal Brief.

III. The Summary of the Invention Was Not Deficient.

The Examiner alleges that the Summary of the Invention section of the Appeal Brief is deficient because Appellants claim an effective treatment for seborrheic dermatitis that is "not limited to a shampoo composition," or "by weakly acidic pH environment." Answer at page 2. Appellants' invention is not so limited.

Appellants made clear in the Appeal Brief that using a low pH shampoo is but "one embodiment of the claimed invention." Appeal Brief at page 2. Appellants' specification also makes it clear that a shampoo is only one of the compositions useful in the claimed methods. Such compositions include "liquid to semisolid pharmaceutical preparations, in particular hair lotions, shampoos, liquid soaps, as well as cream, ointment and gel preparations." Specification at page 5, lines 24-27.

The Examiner further errs by alleging that "the instant claims fail to include all the inventive subject matter as recited in the brief." Answer at page 3. Specifically, the

Examiner describes Appellants' invention as "featuring a composition rinsed away as with a shampoo." *Id.* at page 2 (emphasis added). In this statement, the Examiner mischaracterizes the discussion on page 3 of the Appeal Brief. That discussion compared prior treatments with the claimed invention. Those prior treatments require long-term exposure to compositions that must remain on the skin. On the other hand, the present invention requires only comparatively brief exposure to a single anti-seborrheic dermatitis composition after which the composition can be rinsed away. Appellants' discovery, however, does not require patients to rinse off the composition after any particular exposure.

In any case, Appellants point to their claims, rather than a single section of their Appeal Brief, to define their claimed invention.

IV. The Grouping of Claims Is Correct.

The Examiner acknowledges Appellants' grouping of the claims. Answer at page 3. Accordingly, the claims stand separately as described on page 5 of the Appeal Brief.

V. Appellants Address the Grounds of Rejection.

In the Answer, the Examiner maintains the rejection of claims 38-39, 41-42, 48, 53-54, and 56-66 under 35 U.S.C. § 103 as allegedly being obvious over *Lange* (U.S. Patent No. 5,132,107) alone, or in view of *Durrant et al.* (U.S. Patent No. 4,699,924). Answer at page 4. The Examiner also maintains the rejection of claims 40 and 55 under 35 U.S.C. § 103 as allegedly being obvious over *Lange* and *Durrant et al.* in further view of *Saint-Leger* (U.S. Patent No. 5,650,145). Answer at page 6.

A. The Grounds Do Not Support the Rejection over *Lange* Alone.

The Examiner concludes that "Applicant's claims differ because *Lange* fails to contemplate a example having all the critical elements whereas *Lange*'s suggestion includes all the critical elements for formulating a pharmaceutically effective composition." Answer at page 5. To find the elements of the claimed invention in *Lange*, however, the Examiner has had to redefine certain of those elements.

For example, appealed claims 53-64 require at least one keratolytic agent. To reach those claims, the Examiner alleges that "It is well known in the art that . . . zinc pyridithione . . . [acts as a] keratolytic agent[]." Answer at page 4. This allegation departs from the express teaching of *Lange*, that zinc pyridithione is an "anti-mycotic." *Lange* at col. 7, line 62.

Moreover, *Lange* does not suggest all of the critical elements for formulating a pharmaceutically effective composition. In fact, *Lange* teaches against formulating a single composition. Insisting that his two disclosed compositions must remain separate, *Lange* states that "the simultaneous action of the two previously mentioned compositions included in one shampoo is practically not feasible." *Lange* at col. 2, lines 60-62. Further,

The two formulations of the two-phase shampoo are used in combination and they are suitably packed together but separately, on the one hand because both compositions may not be mixed without loss of effectivity and on the other hand because the synergistic effect of the components used in both liquids is only obtained if they are used one directly after the other!

Lange at col. 6, lines 18-24 (exclamation in original)(emphasis added).

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The Examiner also alleges that *Lange's* teaching of quaternary ammonium compounds, or "quats," suggests the addition of surfactants to *Lange's* Phase II composition. Answer at page 5. But *Lange* does not teach adding surfactants to his Phase II composition. *Lange* expressly teaches away from adding detergents, which contain surfactants, to that composition in column 2, at line 18 ("in the absence of detergents"). *Lange* further teaches away from adding surfactants to the second composition by disclosing that quaternary ammonium compounds, or "quats," are added to enhance "the retention of anti-mycoticum on the skin." *Id.* at col. 8, lines 35-38. Surfactants, such as those included in detergents, do not cause substances to remain behind. Compare definition of detergents in Appeal Brief at fn. 2, page 8. Because *Lange's* "quats" help the anti-mycoticum remain on the skin, one of ordinary skill in the art would conclude that *Lange's* "quats" do not function as surfactants. Accordingly, the skilled artisan would not be taught to add surfactants to *Lange's* Phase II composition, given *Lange's* teaching of "quats."

The grounds of rejection do not provide adequate motivation to modify *Lange*. Motivation, with reasonable expectation of success, exists allegedly "because the techniques for combining these well known components are considered to be conventional knowledge and well within the skilled level of artisan having ordinary skill." Answer at page 5. The Federal Circuit and the Board have reversed rejections resting on both of these grounds. "The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination." M.P.E.P. § 2143.01 (emphasis in original)(citing *In re Mills*, 916 F.2d 680, 16 U.S.P.Q.2d (BNA) 1430 (Fed. Cir. 1990)). Furthermore,

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A statement that modifications of the prior art to meet the claimed invention would have been " 'well within the ordinary skill of the art at the time the claimed invention was made' " because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references.

M.P.E.P. § 2143.01 (emphasis in original)(*quoting Ex parte Levengood*, 28 U.S.P.Q.2d (BNA) 1300 (Bd. Pat. App. & Inter. 1993)). The Examiner has not provided an objective reason to modify *Lange*. Therefore, the Examiner's burden has not been met, and the present rejections should not be allowed to rest on grounds held to be reversible.

B. The Grounds Do Not Support the Rejection over *Lange* in View of *Durrant et al.*

In combining *Durrant et al.* with *Lange*, the Examiner equates dandruff with seborrheic dermatitis without support. "Thus one would have been motivated to make an antidandruff composition useful in seborrheic dermatitis" Answer at page 6. Again, the Examiner continues to overstate what an anti-dandruff treatment would suggest to one of ordinary skill in the art regarding treatment of seborrheic dermatitis.

Appellants protested this overstatement in their Appeal Brief at pages 21-23. To further support the fact that dandruff and seborrheic dermatitis are distinct conditions, Appellants enclose the Declaration of Mitchell S. Wortzman, Ph.D. In his declaration, Dr. Wortzman reviews literature describing dandruff and seborrheic dermatitis and finds that the clinical differences between the two conditions would have caused the skilled artisan to view the conditions, and the treatment of those conditions, as distinct. For example, dandruff is a non-inflammatory condition, unlike seborrheic dermatitis. Also, dandruff does not exhibit the oily, yellowish scales found in seborrheic dermatitis. Thus,

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as stated by Dr. Wortzman, "One of ordinary skill in the art would not find it obvious to use a certain composition to treat seborrheic dermatitis, merely because the same composition is used to treat dandruff." Declaration of Mitchell S. Wortzman, Ph.D., at paragraph 7. Therefore, the skilled artisan would not "have been motivated to make an antidandruff composition useful in seborrheic dermatitis" as alleged by the Examiner.

Additionally, the alleged motivation to combine *Durrant et al.* with *Lange* contrasts with the evidence of-record. The Examiner states:

Thus one would be motivated to make an antidandruff composition useful in seborrheic dermatitis . . . to increase the therapeutic effects because the antiseborrheic effect could be maximized after cleansing the skin and the combining this ingredients in one composition is well within the skilled level of the artisan having ordinary skill in the art, as evidenced by the *Durrant*.

Answer at page 6 (emphasis added). On the contrary, motivation fails because *Lange* teaches that simultaneous action of his cleansing (Phase I) and astringent (Phase II) compositions "included in one shampoo is practically not feasible." *Lange* at col. 2, lines 59-62. Moreover, "both compositions may not be mixed without loss of effectivity." *Id.* at col. 6, lines 20-22. *Durrant et al.* provides no evidence that overcomes these teachings of *Lange*, at least because *Lange* and *Durrant et al.* teach two different methods of treatment. See Appeal Brief at pages 11-14. Furthermore, when motivation rests on being "well within the skilled level of the artisan having ordinary skill in the art," the rejection faces reversal as explained in M.P.E.P. § 2143.01.

The Examiner alleges further motivation resting on notions not supported by substantial evidence. For example, the Examiner asserts that the skilled artisan, knowing the teachings of *Lange* and *Durrant et al.*, "would have been motivated to do so

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[combine *Lange* and *Durrant et al.*] to make the cost-effective product when it combines in one product and improve the compliance that leads to higher therapeutic effects.”

Answer at page 6. No source or support is mentioned for “cost-effectiveness,” “improved compliance,” or “higher therapeutic effects” resulting from improved compliance. This notional evidence does not rise to the level of substantial evidence required by the law. See M.P.E.P. § 2144.03 (*discussing In re Zurko*, 258 F.3d 1379, 1385, 59 U.S.P.Q.2d (BNA) 1693, 1697 (Fed. Cir. 2001); and *In re Lee*, 277 F.3d 1338, 1344-45, 61 U.S.P.Q.2d (BNA) 1430, 1434-35 (Fed. Cir. 2002)).

Finally, the Examiner states that *Lange* suggests the second (Phase II) composition could be used to treat seborrheic dermatitis without the first. The Examiner claims, “the method of treating seborrheic dermatitis could be achieved regardless the first phase composition, especially could be achieved by any cleansing activity in daily life.” Answer at page 6 (emphasis added). *Lange* suggests no such thing. This line of analysis proceeds contrary to established law, because it changes the principle of operation of *Lange*’s two-step treatment. See M.P.E.P. § 2143.01 (*citing In re Ratti* 270 F.2d 810, 123 U.S.P.Q. (BNA) 349 (C.C.P.A. 1959)). *Lange*’s compositions must both be used, and the Phase II composition must be used after the Phase I composition: “The effect of the phase II formulation thus is only reached when used consecutively and almost directly after the cleansing treatment [Phase I] and water rinsing, but before the head skin flora can recover.” *Lange* at col. 6, lines 25-32 (emphasis added). Thus, a skilled artisan would not be motivated to use one of *Lange*’s compositions without the other.

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C. The Grounds Do Not Support the Rejection over *Lange* and *Durrant et al.* in Further View of *Saint-Leger*.

The Examiner has impermissibly expanded the teaching of *Saint-Leger*. The Examiner states, "Saint-Leger teaches that Octopirox or Ciclopirox is effectively used in the treatment of seborrheic dermatitis (see column 2, lines 29-32)." Answer at page 6. However, in the cited passage, *Saint-Leger* actually characterizes Ciclopirox and Octopirox as "antifungal agents." *Saint-Leger* at col. 2, lines 24-31; see also Appeal Brief at page 19. This misstatement departs from the evidence and so fails to support this rejection.

Further, the proffered motivation does not direct the skilled artisan to Appellants' claimed invention. "One would have [been] motivated to [combine the teachings of *Lange*, *Durrant et al.*, and *Saint-Leger*] for better selection or accessibility, and to fit in one's preference." Answer at page 7. Appellants submit that these reasons do not provide the "clear and particular" evidence of motivation required by the Federal Circuit in *In re Dembiczak*, 175 F.3d 994, 999, 50 U.S.P.Q.2d (BNA) 1614, 1617 (Fed Cir. 1999). At most, these reasons make it obvious to try new combinations in general, but would not direct the skilled artisan to consider Appellants' claimed method. Thus, a skilled artisan has not been directed to use Appellants' claimed method, even if the artisan were driven to provide greater selection and accessibility, or to better match patients' preferences.

Finally, motivation cannot derive from merely identifying analogous art. On page 7 of the Answer, the Examiner maintains the argument that motivation can be found, allegedly, since the three cited documents "are drawn to the same technical fields

(constituted with same (or similar) ingredients and share common utilities, and pertinent to the problem which applicant is concerning. MPEP 2141.01(a).” Appellants explained that this rationale identifies, at most, the three cited documents as analogous art. Appeal Brief at pages 19-20. And Appellants showed that merely analogous art does not necessarily provide any motivation to combine that art. *Id.*

VI. Appellants Address the Response to Argument.

The Examiner’s burden in sustaining the obviousness rejections requires her to show that she has found some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the references or to combine reference teachings. Second, the Examiner must show that there is a reasonable expectation of success. Finally, she must verify that the prior art reference (or references when combined) teach or suggest all of the claim limitations. M.P.E.P. § 2143. Appellants contend that the Examiner has not met this burden.

A. The Answer Contains Unsupported Assertions.

Throughout the Response to Argument section starting on page 7 of the Answer, the Examiner makes many blunt assertions without evidence. Often, these baseless assertions provide the foundation on which the rejections rest. The Examiner generally provides no evidentiary support for these assertions, occasionally referring to “conventional wisdom,” common knowledge, or the level of ordinary skill in the art. The following chart lists these unsupported assertions.

| Examiner's Assertion | Examiner's Support |
|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|
| An anti-dandruff composition would be useful to treat seborrheic dermatitis. Answer at page 6. | None. <i>See id.</i> <i>Contrast</i> , Declaration of Mitchell S. Wortzman, Ph.D., at ¶ 8. |
| <i>Lange's</i> two compositions suggest only one. Answer at pages 7-8. | "Conventional wisdom." <i>Id.</i> at page 8. |
| Zinc pyridithione is a keratolytic agent. Answer at page 9. | "It is well known." <i>Id.</i> <i>Contrast</i> , "zinc pyridithione as anti-mycotic." <i>Lange</i> at col. 7, line 62. |
| "One would have been motivated to include a small amount of 'quat' into phase II composition to enhance therapeutic efficacy." Answer at page 9. | None. <i>See id.</i> |
| <i>Lange's</i> "quats" are "surfactants." Answer at page 9. | None. <i>See id.</i> |
| Motivation to use <i>Lange's</i> Phase II composition to treat seborrheic dermatitis alleged because "the additives are utilizing different biological pathway" "without causing the toxicity" "but lowering effective dose" and "reducing undesired side effect." Answer at page 9. | None. None. None. None. <i>See id.</i> |
| "Thus, knowing anti-seborrheic effect from <i>Lange's</i> teaching, one would have been motivated to make a single composition (e.g. hair formulation) having all the said critical components in a weakly acidic environment to reduce skin irritation while the composition maintains its therapeutic effectiveness from active agents (e.g. antimycotic (piroctone olamine), keratolytic, etc.)" Answer at pages 9-10. | None. <i>See id.</i> |

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As discussed below, these bald assertions do not provide the substantial evidence necessary to support a *prima facie* case of obviousness and a denial of a patent to deserving inventors. See M.P.E.P. § 2144.03 (discussing *In re Zurko*, 258 F.3d at 1385, 59 U.S.P.Q.2d (BNA) at 1697; and *In re Lee*, 277 F.3d at 1344-45, 61 U.S.P.Q.2d (BNA) at 1434-35. In the words of Dr. Wortzman,

The Examiner has not addressed the substance of the cited literature, and does not appear to speak on the basis of her own research or clinical experience. Without any basis for her rejection of the well-settled understanding of those in the art, I cannot know why she has taken this mistaken position, how to explain the source of her error, or what evidence would convince her that her position is incorrect. The most that one can say is that the Examiner appears to have taken a position on the basis of her own belief that is contrary to the scientific literature of record and my own long experience in the field.

Declaration of Mitchell S. Wortzman, Ph.D., at ¶ 8. Rejections built on anything other than the substantial evidence required by law should be reversed.

B. The Examiner's Admission about *Lange* Applies.

The defect in the teaching of *Lange* admitted by the Examiner applies in the present case. "This examiner agreed on that the *Lange* reference has defect." Interview Summary dated October 1, 2002. That defect comes from the fact that *Lange* teaches two compositions (which do not work when combined), while Appellants' claimed invention needs only a single composition. One of ordinary skill in the art, taking *Lange* as a whole, would not be motivated to make just one composition. This makes *Lange* defective as a reference against Appellants' claimed invention.

In the Answer, the Examiner tries to qualify her admission during the interview by saying, "the said admission is agreed conditionally on the basis that [appellants'] invention is consisting of one phase composition." Answer at page 7. The qualification

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is inapposite, since it follows from the Examiner's misinterpretation of *Lange* as teaching a two-phased, single composition. The misinterpretation can be seen in the words used in the Answer: "[Appellants'] argument during the interview was about that Lange's two phase composition can't be feasible and different from [Appellants'] one phase composition." Answer at page 7. Appellants would clarify that statement in this manner: "Appellants argued during the interview that combining *Lange*'s Phase I composition and Phase II composition is not 'feasible' (*Lange* at col. 2, line 62), and that *Lange*'s compositions differ from Appellants' single composition." It appears the Examiner is using "phase" in the chemical sense of the word, and this is an incorrect reading of *Lange*.

Nowhere does *Lange* use "phase" in the chemical sense of the word to indicate immiscible ingredients such as oil and water in a salad dressing. Instead, *Lange* uses the word "phase" to mean a step or stage of his two-step treatment. The Examiner's use of the words "one phase composition" thus is meaningless if the chemical sense of the word "phase" is assumed. Appellants claim methods that use a single composition containing certain ingredients, whereas *Lange* teaches two compositions used sequentially, neither of which contain all of those certain ingredients. Thus, *Lange* is defective as a reference against Appellants' claimed invention.

This defect is significant. *Lange* teaches a two-composition treatment system that does not teach or suggest a one-composition treatment system. One of ordinary skill in the art would not be motivated to abandon one or the other of *Lange*'s compositions. Nor would they reasonably expect success in employing only one of *Lange*'s composition to treat seborrheic dermatitis. Similarly, the skilled artisan would

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not be motivated to combine *Lange*'s two compositions, at least because *Lange* teaches away from such combinations. See, e.g., *Lange* at col. 2, lines 59-62. Also, the skilled artisan would not reasonably expect success using a combined composition from *Lange*'s teachings, because, for example, *Lange* states that such a combination would cause his compositions to lose their "effectivity." *Id.* at col. 6, lines 20-22.

The defect in *Lange* cannot be remedied with conventional wisdom. Yet the Examiner asserts that it can. Answer at pages 7-8. Conventional wisdom does not satisfy the Examiner's burden. Further, Appellants contend that conventional wisdom actually speaks in favor of patentability, since Appellants have proceeded against the conventional wisdom. See Appeal Brief at page 9. Specifically, Appellants have shown that a composition comprising surfactants and having a lower pH, among other ingredients, is practically feasible, in particular for the treatment of seborrheic dermatitis. Contrast, *Lange* at col. 2, lines 55-62.

C. Appellants' Claims Do Not Read on *Lange*'s Two Compositions.

The Examiner's misinterpretation of *Lange*'s two "phases" manifests itself again at page 8 of the Answer. The Examiner points to Appellants' use of the claim term "comprising" to encompass "*Lange*'s patented shampoo composition having two phases." *Id.* However, Appellants respectfully contend that the broadest reasonable interpretation of their claim language "a composition comprising [listed ingredients]" cannot read on *Lange*'s two separate compositions, neither of which alone has all of the listed ingredients.

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D. Appellants' Claims Do Not Read on *Lange*'s Phase II Composition Containing "Quats."

The Examiner contends that "[e]ven if *Lange*'s composition is consisting of two compositions, one of *Lange*'s two composition suggest all the critical elements."

Answer at page 8. However, *Lange* does not teach or suggest including surfactants in his Phase II composition. As explained above on page 5, *Lange*'s "quats" do not function as surfactants, because they allow anti-mycotic to remain behind.

Further, *Lange* names substances possibly containing a quaternary nitrogen, but *Lange* characterizes them as something other than "surfactants." For example, *Lange* discloses "Polyquaternium 17 (Mirapol AD-1)," which *Lange* describes as a "conditioner," not as a surfactant. *Lange* at col. 8, line 7. Also, "cocodiamoniumcollagene hydrosylate" is a "protein conditioner." *Id.* at col. 8, lines 49-50. Thus, *Lange* does not direct the skilled artisan to add surfactants to his Phase II composition. Extrapolating *Lange*'s teaching of "quats" to mean surfactants requires a leap not supported by substantial evidence.

E. The Additional Evidence for Motivation to Modify *Lange* Fails.

One would be motivated to modify *Lange*, claims the Examiner, because "the additives are utilizing different biological pathway so that they could assist the active agent without causing the toxicity but lowering effective dose and reducing undesired side effect." Answer at page 9. The Examiner provides no hint, however, where the alleged prior art discusses biological pathways, toxicity, effective dose concentration, or undesired side effects. The Examiner's mind cannot provide the substantial evidence for modifying *Lange* and denying Appellants their patent. See M.P.E.P. § 2144.03.

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F. The Examiner Again Extrapolates Anti-Dandruff Therapy.

Allegedly, "deficiencies [of *Lange* have] been remedied because Durrant teaches antidandruff hair cream composition (single composition)." Appellants respectfully maintain that an anti-dandruff treatment does not teach or suggest an anti-seborrheic dermatitis treatment. Dandruff and seborrheic dermatitis are two distinct conditions having distinct symptoms. Dandruff is "a 'noninflammatory' scaling of the scalp, while 'seborrheic dermatitis is an inflammatory, erythematous, and scaling eruption that occurs' " in many areas, not just the scalp. Declaration of Mitchell S. Wortzman, Ph.D., at ¶ 5 (quoting MANUAL OF DERMATOLOGIC THERAPEUTICS 164 (5th ed. 1995)). Moreover, even if the dandruff-like symptoms of seborrheic dermatitis respond to dandruff treatments, treating a symptom does not necessarily teach or suggest treating the more serious underlying condition. See Appeal Brief at pages 21-22.

G. *Saint-Leger's* Words Are Impermissibly Expanded.

Again, the Answer repeats, "Saint-Leger teaches that Octopirox or Ciclopirox is effectively used in the treatment of seborrheic dermatitis (see [*Saint-Leger* at] column 2, lines 29-32)." Answer at page 10. Appellants challenge this characterization by referring to the words actually used in *Saint-Leger*. These two compounds are described as "antifungal agents." *Saint-Leger* at col. 2, lines 25 and 33. Antifungal agents do not obviously provide a treatment for seborrheic dermatitis. See specification at page 1, lines 30-37.

H. More Options Make Modification Merely Obvious to Try.

The Examiner alleges additional motivation to modify *Lange*, *Durrant et al.* and *Saint-Leger*: "Thus, one would have been motivated to make such modification

because it is always desired to have more selection option to satisfy patient's needs." Answer at page 10. At best, this renders the proposed modification obvious to try. And, it does not provide the "clear and particular" evidence necessary to select Appellants' claimed invention. See *In re Dembiczak*, 175 F.3d at 999, 50 U.S.P.Q.2d (BNA) at 1617.

I. "Particular or Difficult" Is Not the Standard for Obviousness.

The Examiner concludes the discussion of *Saint-Leger* with: "the said modification [pH adjustment] is not considered to be particular nor difficult, and is obvious to one of ordinary skill in the art to practice with reasonable expectation of success." Answer at page 10. Appellants respectfully contend that "particular or difficult" does not figure into the standard for patentability provided by 35 U.S.C. § 103.

Furthermore, in the present case, "reasonable expectation of success" does not apply to just one element of a claimed invention. Rather, the reasonable expectation of success measures whether the skilled artisan would reasonably expect success in an art-motivated attempt to make the claimed invention as a whole. In the present case, the skilled artisan would not have reasonably expected success in Appellants' claimed methods based on the cited documents. In fact, evidence suggests that treating seborrheic dermatitis with 1-hydroxy-2-pyridones was, at most, merely obvious to try even long after Appellants' priority date. See Appeal Brief at page 22.

VII. Conclusion

For all of the reasons discussed above, Appellants submit that the Examiner has not established a *prima facie* case of obviousness against the appealed claims.

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Therefore, Appellants respectfully request that the pending rejections be reversed, and pending claims 38-42, 48, and 53-66 be allowed.

If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 that are not enclosed herewith, including any fees required for any extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,
FINNEGAN, HENDERSON, FARABOW,
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Dated: June 9, 2003

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